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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,930	09/06/2005	Lone Andersen	05198-P0010A	6400
24126 7590 01/05/2010 ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET STAMFORD, CT 06905-5619				
EXAMINER				
DEES, NIKKI H				
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1794				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,930

Applicant(s)

ANDERSEN ET AL.

Examiner

Nikki H. Dees

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-8, 10-16, 19, 20, 23, 24, 26-43 and 45-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-8, 10-16, 19, 20, 23, 24, 26-43 and 45-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The Amendment filed on October 26, 2009, has been entered. Claims 1, 2, 4-8, 10-16, 19, 20, 23, 24, 26-43, and 45-64 are currently pending in the Application. Claims 3, 9, 17, and 18 have been cancelled. The previous objections to and rejections of claims 3, 9, 17, and 18 have been withdrawn in view of the cancellation of claims 3, 9, 17, and 18.
2. The previous objections to claims 1, 6, 12, 27, 29, and 37 have been withdrawn in view of the amendments to these claims. The previous 112 rejection of claim 1 regarding the use of the term "substantially" has been withdrawn in view of Applicant's arguments. The previous 112 rejection of claims 4, 5, 10 and 17 regarding the use of the term "comonomer" have been withdrawn in view of Applicant's arguments. The previous 112 rejections regarding the lack of antecedent basis of claims 4 and 5 have been withdrawn in view of the amendments to claim 1. The previous 112 rejection of claim 6 has been withdrawn in view of the amendment to claim 6. The previous 112 rejection of claim 19 has been withdrawn in view of the amendment to claim 19.
3. The previous 102 rejection of claims 1-16, 23, 24, 26-41, 45-50, 55 and 57-64 over Goldberg et al. have been withdrawn in view of Applicant's amendments to claim 1.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 4-8, 10-16, 19, 20, 23, 24, 26-41, 45-50, 55 and 57-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (WO 01/47368).

6. Regarding claims 1, 2, 4-8, 10-16, and 58-64, Goldberg et al. disclose a chewing gum, free of non-biodegradable polymers (p. 17, ¶5), including a multifunctional polyol initiator (p. 17, ¶4) and two different monomers (p. 17, ¶1) forming the backbone of a biodegradable chewing gum polymer as claimed by applicant. Goldberg et al. teach carbonate monomers, ϵ -caprolactone and δ -valerolactone (pp. 11-12).

7. Goldberg et al. teach that the different monomers may be present in their invention at 51-99 wt % of the first monomer (p. 13 lines 9-14) and 0.1 to 40 wt % of the second monomer (p. 16 lines 17-24). Goldberg et al. also teach that "the optimal level of the second monomer will depend on the specific structure of the second monomer and can be determined by those skilled in the art." They further state that one or more monomers from the first and second groups may be present in the polymers of their invention (p. 17 lines 1-3).

8. Goldberg et al. are silent as to the specific amounts of the monomers as required by claim 1. They are also silent as to the amount of initiator required in their invention and the changes that result in the adjustment of the amount of the initiator.

9. Regarding claim 1, as Goldberg et al. provide ranges overlapping those claimed by Applicant for the amount of monomers to be present in the polymer of their invention, as well as teach that the artisan would have been able to determine the amount of monomers to incorporate depending on the final polymer desired, the arrival at the ranges of polymers as claimed is considered to have required no more than routine experimentation based on the teachings of the prior art.

10. Similarly, regarding claims 19 and 20, as Goldberg et al. provide for the use of initiators as claimed, one of ordinary skill would have been able to determine the appropriate initiator, as well as the amount of initiator, to utilize in the polymer in order to result in a biodegradable polymer having the desired characteristics. The adjustment of the initiator would additionally result in the desired rheological properties of the chewing gum polymer as claimed. The determination of the type, amount, and functional number of the initiator would have been well within the abilities of one of ordinary skill in the art at the time the invention was made.

11. Regarding claims 23 and 24, the monomers have molecular weights within Applicant's claimed ranges (p. 10 lines 1-4).

12. Regarding claims 26-32, Goldberg et al. teach flavoring agents in the chewing gum including essential oils and extracts (p. 7, ¶2). Specific examples teach flavoring

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agents (peppermint flavors) present in the chewing gum at 1.8 wt%, anticipating Applicant's claimed range (Example 48, Chewing Gum Formulation).

13. Regarding claims 33-38, Goldberg et al. teach sweeteners for use in their chewing gum including bulk sweeteners (p. 6 lines 29-30; p. 7 lines 11-14). Example 48, Chewing Gum Formulation teaches the presence of bulk sweeteners (sorbitol and mannitol) at about 55 wt %. The high intensity sweetener aspartame is present in an amount of about 1 wt%, anticipating applicant's claimed ranges.

14. Regarding claims 39-41, Goldberg et al. teach softeners for inclusion in their chewing gum. Softeners taught include palmitic acid and stearic acid, among others. The softeners are generally present in amounts up 18 % by weight of the chewing gum base, indicating they would inherently be present in Applicant's claimed amount in the chewing gum product (p. 5).

15. Regarding claims 45 and 46, Goldberg et al. teach fillers for inclusion in their chewing gum products at up to 60 % by weight of the chewing gum base (p. 5 ¶2-p. 6 lines 1-2).

16. Regarding claim 47, Goldberg et al. teach coloring agents for inclusion in their chewing gum product (p. 6 line 4).

17. Regarding claims 48-50 and 55, the chewing gum in Goldberg et al. may be coated with a syrup, which results in a hard or soft coating (p. 9 ¶1-2).

18. Regarding claims 57, 61, and 62, Goldberg et al. teach conventional chewing gum polymers and resins for use in their invention (pp. 4-5).

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19. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (WO 01/47368) in view of Li et al (6,153,231).
20. Goldberg et al. teach a chewing gum product as detailed above.
21. Goldberg et al. are silent as to the inclusion of active ingredients in the chewing gum product.
22. Li teaches active ingredients for inclusion in chewing gum products (col. 7, lines 60-61).
23. One of ordinary skill in the art at the time the invention was made wishing to provide a chewing gum comprising active agents would have found it obvious to include a pharmaceutical agent in the chewing gum of Goldberg et al since it is conventional to include such an active ingredient in chewing gum, as evidenced by Li et al.
24. Claims 51-54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (WO 01/47368) in view of Meyers (5,433,960).
25. Goldberg et al. teach a chewing gum product as detailed above.
26. Goldberg et al. are silent as to the chewing gum product comprising coating components and film forming agents as required by claims 51-54 and 56.
27. Regarding claim 51, Meyers teaches the coating of the chewing gum with low calorie bulking agents and polyols. One of ordinary skill would have recognized that the claimed polyols are commonly used as coating agents in the chewing gum art.
28. Regarding claims 52-54 and 56, Meyers teaches an outer coating of a chewing gum comprising sugar-free sweeteners and flavors (col. 11 lines 11-46).

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29. One of ordinary skill in the art at the time the invention was made wishing to provide a chewing gum with a sweetened and/or flavored coating would have found it obvious to coat the chewing gum in Goldberg et al. with a coating as claimed by applicant in order to provide storage stability to the chewing gum since it is well known to coat chewing gum products with each of applicant's claimed coating materials in order to achieve this objective, as evidenced by Meyers.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 1, 2, 4-8, 10-16, 19, 20, 23, 24, 26-43, and 45-64 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being

unpatentable over claims 1-62 of copending Application No. 10/472,122; claims 1-66 of copending Application No. 10/528,926; claims 1-7, 14-26, 28-31, and 33-57 of copending Application No. 10/528,927; claims 1-20, 22, 23, 25, 26, 28-30, and 36-42 of copending Application No. 10/529,133; claims 1, 3-7, and 9-55 of copending Application No. 10/529,137; and claims 1, 10, 11, 13-18, 24-26, 28-39, and 41-54 of copending Application No. 11/088,109 each set of claims being in view of Goldberg et al. Although the conflicting claims are not identical, the use of multifunctional polyol initiator in preparing the biodegradable chewing gum polymers claimed in each of the conflicting applications would have been obvious to one of ordinary skill as the use of multifunctional polyol initiators is well known in making claimed biodegradable polymers, as evidenced by Goldberg et al.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

32. Applicant's arguments filed October 26, 2009, have been fully considered but they are not persuasive.
33. Applicant argues that the teachings of Goldberg are not sufficiently specific to have directed one of ordinary skill to have arrived at the claimed invention (Remarks, p. 20-21).
34. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257,

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191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (MPEP § 2144.05 (I)). As Goldberg et al. teach ranges for monomers/comonomers which overlap with the claimed ranges for monomers/comonomers to be used in chewing gum bases, the instant claim 1 is considered obvious over the teachings of Goldberg. Applicant has not provided any evidence of unexpected results present in the claimed range of monomer, comonomer, or initiator. Indeed, as Goldberg et al. teach biodegradable polymers suitable for inclusion in chewing gum comprising monomers, comonomers and initiators as claimed, the instant invention is considered obvious over the teachings of the prior art.

35. The advantages of the instant invention as provided by Applicant at p. 22 of the Remarks are not considered to render the instant invention unobvious over the teachings of Goldberg. Again, as Goldberg et al. teach biodegradable polymers specifically for inclusion in chewing gum comprising monomers, comonomers and initiators as claimed, the properties that Applicant regards as improvements over the prior art are considered to be resultant from obvious variations of the prior art.

36. It is noted that Applicant does not address the double patenting rejections in the Remarks filed October 26, 2009.

Conclusion

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday from 7:30 AM to 5:00 PM (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/N. H. D./

Nikki H. Dees
Examiner
Art Unit 1794

/KEITH HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794